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|---|---|
| STARSIAK, JOHN S | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1753 | 9 |

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/711,277 | Jose A. Olivaries<br>Peter C. Stark |
| **Examiner** | **Group Art Unit** |
| J. STARSIAK | 1753 |

*—Th MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—*

**P riod for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

☒ Responsive to communication(s) filed on 07 July 2003.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

**Di position of Claims**

☒ Claim(s) 1-50 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-26 and 28-50 is/are rejected.

☒ Claim(s) 27 is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement

**Application Papers**

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Pri rity under 35 U.S.C. § 119 (a)-(d)**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

**Attachment(s)**

☐ Information Disclosure Stat ment(s), PTO-1449, Paper N (s). _____

☐ Int rvi w Summary, PTO-413

☐ Notice of Ref rence(s) Cited, PTO-892

☐ Notice of Inf rmal Pat nt Application, PTO-152

☐ Notice of Draftsperson's Pat nt Drawing R vi w, PTO-948

☐ Oth r _____

**Office Action Summary**

## DETAILED ACTION

### *Claim Rejections - 35 U.S.C. § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-22, 24- 26, and 29-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanning et al. in view of Beale & Sudmeier.

Hanning et al.. teaches [ABSTRACT]: " a new laser-fluorescence detector for capillary electrophoresis (CE) is described. The detector is based on transverse illumination and collection of the emitted fluorescent light via total internal reflection along the separation capillary. The capillary is coated with a low refractive index fluoropolymer and serves as a liquid core waveguide (LCW). The emitted light is detected end-on with a CCD camera at the capillary exit....Full four-color DNA sequencing is also demonstrated.... The concept should be highly suitable for capillary array detection.". Hanning et al. teaches [page 3424, left-hand column]: "The separation capillary is externally coated with a polymer (Teflon AF, Du Pont, Wilmington, DE) with a lower refractive index (RI) than the separation medium.". Hanning et al. teaches [page 3425, left hand column]: " The laser was operated at 30 mW.". Hanning et al. teaches [page 3425, left-hand column]: "In this way, the 10-90% intensity width of the laser beam in the axial direction at the capillary was estimated to be 25$\mu$m.". Hanning et al. teaches [page 3425, left-hand column]: " In the gel electrophoresis experiments the capillary was filled with a viscous 7.0 % (w/v) solution of linear poly(dimethylacrylamide) in a 1× TBE (0.1 M tris, 0.1 M borate, 2 mM EDTA), 7M urea buffer". Hanning et al. teaches [page 3424, right-hand column and page 3425, left-hand column]: The emitted fluorescent light was guided ~50 mm to the end of the capillary. The end of the capillary was placed in a liquid-filled chamber. The opposite wall of which was made of planar glass plate, at the focal point of a 27-mm-focal width *f*/0.9 aspheric condenser lens....The primary light was absorbed by one or more glass filters.... Finally, the capillary end was imaged by a 50-mm camera objective....onto a thermoelectrically cooled CCD camera....The

collected images were stored and evaluated by means of WinView software....on an IBM-compatible PC. Hanning et al. teaches [page 3425, left-hand column]: " The length of the gel-filled capillary from the injection end to the illumination zone was ~300 mm.". Hanning et al teaches [page 3425, left hand column]: " The sample was injected at 4 kV for 20 s and electrophoresed at 5 kV.". The only significant difference between the claims and Hanning et al. is that the light source in Hanning et al. is stationary with respect to the capillary and the claims recite the light source scans the capillary along the longitudinal axis of the capillary. Beale & Sudmeier teaches scanning the light source along the longitudinal axis of the capillary has advantages over a stationary light source. Specifically Beale & Sudmeier teaches [page 3367, left-hand column]: "The capability to monitor the progress of the separation process or to dynamically alter the length of the separation bed by scanning the entire capillary offers several advantages over conventional instrumentation. Separation time can be optimized since the duration of the run need only be long enough to resolve the components of interest. Thus, sample throughput will be increased as the solutes do not need to migrate through the entire length of the separation bed.". It would have been obvious to one of ordinary skill in the art at the time of the invention to add means for scanning the light source to the device of Hanning et al. to increase throughput.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hanning et al. in view of Beale & Sudmeier as applied to claim 19 above, and further in view of Li et al.

The device of Hanning et al is illustrated only schematically. Li et al discloses a liquid core waveguide detector in detail. In Li et al. (see Fig. 1) the emitted light passes from the end of the capillary through a fiber optic to the photodiode. The fiber optic allows emitted light to pass out of the cell while forming part of the cell wall (no liquid can flow out of the cell). Also, the use of a fiber optic allows flexibility of the location of photodetecting elements of a liquid core wavelength detector, i.e. the photodetecting elements do not need to be aligned on the longitudinal axis of the capillary and more of the light exiting the end of the capillary would reach the CCD camera. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the device of Hanning et al. with a fibre optic because of the reasons recited above.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hanning et al. in view Beale & Sudmeier as applied to claim 19 above, and further in view of Kim et al..

In Beale & Sudmeier an interference filter and an edge filter are used to prevent any light except light emitted by the fluorescent label from reaching the photomultiplier tube. The use of narrow bandpass filter to preform the same function is well-known in the laser-induced fluorescence detection art, i.e. Li et al. is one of many examples. Specifically, Li et al. teaches [page 938, left-hand column]: "Band-pass filters 10 nm in width, centered at 540, 560, 580, and 610 nm ... selectively transmit the fluorescence generated from C, A, G, and T fragments to a photomultiplier tube (PMT) detector, respectively. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute a narrow bandpass filter for the

combination of the interference filter and the edge filter of Beale & Sudmeier because they perform the same function.

***Response to Arguments***

Applicant's arguments filed 07 July 2003 have been fully considered but they are not persuasive.

Applicant's arguments are not well-taken for the following reasons. First, the applicant's main argument is that because there are differences between the secondary references and the claimed invention/Hanning et al. (the primary reference) the 103 rejections are improper. However, the applicant fails to specifically point out why these differences would render the modifications of Hanning et al in view of the secondary references non-obvious. Second the applicant's most detailed argument is that since Beale & Sudmeier recites removing the polyimide coating from the capillary tube, Beale & Sudmeier teaches away from having a polymer coating on the capillary. This is not well-taken because Hanning et al teaches that the invention should not be fabricated from capillaries with coated with polyimide since this would entail removing the polyimide coating and coating the capillaries with a material such as Teflon. Specifically, Hanning et al teaches [page 12, line 36 to page 13, line 7]: "The most common coating material for CE capillaries is polyimide. This material is fluorescent and not transparent, and has to be removed before excitation. The removal of the coating involves an extra, complicated manufacturing step. After removal of the coating, the capillaries are mechanically very fragile, and the surface of the

capillaries is sensitive to dirt and scratches. Small, remaining polyimide particles, may give rise to large amounts of light scattering and background.". Also, it appears that the applicant argument is based on a more extensive modification of Hanning et al in view Beale & Sudmeier than is actually set forth in the rejection. Third, applicant's argument directed to Li et al is not well-taken because it focuses on minor differences between Hanning et al. and Li et al. which are not directly related to the rejection of the claim. Fourth, applicant's argument directed to Kim et al is to recite particulars in the claim not found in Kim et al. and to state therefore the modification of Hanning et al. in view of Kim et al. is not obvious. If this line of reasoning were correct there would be no 103 rejections on 102 rejections. In none of his arguments does the applicant directly address the reasons for obviousness set forth in the rejections above.

***Allowable Subject Matter***

Claim 27 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art does not explicitly teach or fairly suggest a device for separating and detecting particles comprising: a capillary having a first end and a second end, the capillary filled with a buffer solution; a first reservoir in fluid communication with the first end of the capillary, the first reservoir configured to contain buffer solution; a second reservoir configured to contain

buffer solution; an electrical source for applying a voltage across the capillary, the voltage causing a fluorescently labeled particle positioned within the capillary to travel from a first location within the capillary to a second location within the capillary; an excitation source for directing an excitation beam onto the capillary, such that when a fluorescently labeled particle is positioned within the capillary, the fluorescently labeled particle emits light after excitation with the excitation beam, the excitation source capable of exciting fluorscently labeled particles at more than one position along the capillary; a light detector positioned to collect fluorescent light emitted from the excited fluorescently labeled particle located within the capillary, wherein the light detector comprises low-level light detection electronics and *a high band pass filter for filtering light with a wavelength greater than about 500 nm and a notch filter.*

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Starsiak Jr. whose telephone number is (703) 308-1797. The examiner can normally be reached on Monday to Wednesday from 8:00 AM to 3:30 PM and on Thursday and Friday from 8:00 AM to 12:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

NAM NGUYEN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

John S. Starsiak Jr.

27August 2003